

Genetics Privacy and Discrimination Legislation:

The current patchwork of federal and state laws regarding genetic privacy and discrimination in employment, health care, and insurance provides examples of a wide variety of legislative approaches to regulation of the use, collection, or distribution of individuals' genetic information. This overview of genetics legislation briefly explains some federal legislation affecting the use of genetic information in the health insurance and employment contexts. Next, this summary looks at genetic legislation enacted by the states. State laws are compared in the attached tables that separately examine privacy, health insurance, employment discrimination, and life and disability insurance genetics laws. This text attempts to provide some context for the comparative analyses presented in state-by-state comparative tables.

The National Conference of State Legislatures (NCSL) has recently completed a three-year project to analyze state and federal genetics legislation. The project was a collaborative effort by the Georgetown University Law Center (GULC) and the NCSL, and was funded by the National Institutes of Health. The joint GULC-NCSL project is designed to provide objective, non-partisan information to aid legal and policy development of genetic issues. This summary relies heavily on the research of this project, which is available at www.ncsl.org/programs/health/genetics.htm, and is additionally published in the project's report: Lawrence O. Gostin et al., *Genetics Policy and Law: A Report for Policymakers* (National Conference of State Legislatures 2001). Additional sources for this analysis and resources for further investigation are listed in the selected bibliography at the end of this document.

FEDERAL LEGISLATION AND POLICY:

No federal legislation has been passed relating to genetic discrimination in individual insurance coverage or genetic discrimination in the workplace. Additionally, no federal legislation explicitly guarantees the privacy of genetic information. Several bills have been introduced during the last decade seeking to regulate genetic discrimination and/or privacy. Some of these bills attempted to amend existing civil rights and labor laws, while others stood alone. In parallel with Congressional efforts, the executive branch has issued rules providing for protection of genetic information by agency rulemaking and executive order. Protections against insurance and employment discrimination have been developed within general laws on these topics, however, federal protections for genetic privacy and discrimination are widely regarded as incomplete. Two principle laws that provide protections for genetic information in the health care and employment settings are described below.

Health Insurance:

Congress first passed specific controls on the use of genetic information in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA prohibits health insurance discrimination based on any "health status-related factor," including genetic information. The legislation also limits exclusions for preexisting conditions to 12 months, and states explicitly that in the absence of a current diagnosis of illness, genetic information shall not be considered a preexisting condition. HIPAA guarantees a minimum level of protection, as state laws that provide additional protections are not preempted by the federal legislation.

An important limitation to HIPAA coverage, is that the act is limited in its application. HIPAA regulates only group health plans, and has no effect in the individual health insurance market. HIPAA applies to both group health insurance plans from insurance companies (those regulated by states) and self-insured health insurance plans (those regulated by the federal government). The scope of the genetic protections offered by HIPAA is also selective, rather than comprehensive. While prohibiting genetic discrimination broadly, HIPAA doesn't limit insurers' access to genetic information. The act also is silent on the use of genetic information to rate or price policies. The regulations that develop standards related to anti-discrimination under HIPAA prevent group health plans from denying eligibility or charging higher premiums based on factors including an individual's genetic information.

Privacy:

The Health Insurance Portability and Accountability Act also provided that the Department of Health and Human Services issue regulations protecting the privacy of medical and personal health information. The regulations were mandated when Congress failed to pass comprehensive privacy legislation (as required by HIPPA) by 1999. The new standards limit the non-consensual use and release of private health information. They give patients new rights to access their medical records and to know who else has accessed them. The standards also restrict most disclosures of health information to the minimum needed for the intended purpose. They establish new criminal and civil sanctions for improper use or disclosure. The standards also create new requirements for access to records by researchers and others. These medical information standards are not specific to genetics, rather they are sweeping regulations governing all personal health information. These privacy regulations became effective on April 12, 2001, by order of President Bush. (HIPPA National Standards to Protect Patients' Personal Medical Records, Dec. 2000.)

Employer's use of genetic information:

While federal legislation prohibiting employer discrimination was not drafted to specifically prohibit misuse of genetic information, the language of the Americans with Disability Act of 1990 (ADA) includes broad language prohibiting discrimination based on disability. Title I of the ADA prohibits discrimination against individuals who are

regarded as having a disability, as well as against persons with symptomatic disabilities. These restrictions are based on the perception or symptoms of a disability, regardless of its cause.

In March 1995, the Equal Employment Opportunity Commission (EEOC), which enforces and interprets the ADA, issued an interpretation of the statute. The EEOC Order states that genetic discrimination is unlawful when “genetic information relating to illness...” causes an individual to be regarded as having a disability. (EEOC Compliance Manual, vol. 2, EEOC Order No. 915.002, Definition of the term disability (1995) (p32-33)) The EEOC guidance is policy guidance that does not have the same legally binding effect on a court as a statute or regulation; and the guidance has not been tested in court. Additionally, recent Supreme Court cases have substantially limited the scope of protection under closely related provisions the ADA. Therefore, the EEOC guidance is limited in scope and legal effect.

Former President Bill Clinton issued Executive Order No. 13145 in February, 2000, prohibiting discrimination against civilian federal government employees based on “protected genetic information.” The executive order states administration policy. It does not create any right to sue for violation of the terms of the order. In July, 2000, the EEOC issued guidance on this executive order, noting that federal employees may be able to sue under the ADA. EEOC Order No. 915.002 (2000). Such a suit, however, would be subject to the limitations discussed above.

STATE LEGISLATION:

The following brief overview of existing state genetics law attempts to highlight some of the similarities and differences between genetics legislation in various states. Comparisons of the legislation of the states are provided in tables from the National Conference of State Legislatures. (Tables 1 to 4, attached). This comparison of the states’ genetics laws divides the legislation into subject matter categories, considering privacy of genetic information separately from discrimination in health insurance, life and disability insurance, or employment based on use of genetic information. According to the NCSL’s data, all but four states (Mississippi, Pennsylvania, Utah, and Washington) had enacted genetics legislation by the fall of 2001.

The 46 states that have chosen to enact genetics legislation have adopted widely divergent approaches to regulating genetics information. These statutes begin with widely divergent definitions of the scope of what is protected by genetics laws. Some states use a narrow definition of genetic information. For example, a number of state statutes limit discrimination based only on “the results of a genetic test” defined as examination of an individual’s genes or gene products. (Texas and Georgia are examples of this approach to coverage.) Other states have broadly defined genetic information, so that the term also includes information from family medical histories, genetic test results of family members, and inherited characteristics. (Virginia and New Jersey are examples of this broad scope.) Still another group of states have tried to limit these broad

definitions by excluding results of routine physical or chemical tests, indirect manifestations of genetic disorders, and/or accepted scientific practices. (See Michigan, Arkansas, and Florida.) These coverage distinctions can be compared in health insurance legislation: Table 1, column 7. Also, information on the scope of coverage of employment discrimination statutes is conveyed in columns 2 to 6 of Table 3. These coverage distinctions are a primary means of varying the reach of a genetics statute.

In addition to coverage, existing state genetic information privacy and nondiscrimination laws also differ in the protections they afford and in their enforcement schemes. Access, storage, and distribution of genetic information may be regulated. Additionally, some states provide for specific private or public enforcement of the anti-discrimination or privacy measures. Many of these differences are highlighted in Tables 1 to 4. Further discussion is also provided below, to explain the different protections offered within specific areas of legislation.

Some of the variation between the state laws can be traced to the date of states' enactment of genetics legislation. National thinking on genetics legislation has changed over time, and state statutes, in some ways, reflect changing policy concerns. While many of the first attempts to protect against the misuse of genetic information were tied to specific disorders such as sickle cell trait, most recent statutes address the use of genetic testing or genetic information without reference to specific diseases. In the 1990's many states passed laws that specifically regulate the use of genetic information, treating it differently than other healthcare information or other personally identifiable information. A few states have incorporated protections of genetic test results or other genetic information into existing, broad anti-discrimination statutes. The federal HIPAA legislation and its privacy regulations propagated by the DHHS use this approach.

Separating the discussion of genetics legislation into topics facilitates comparison of the laws of the 50 states, although the survey has some inherent limitations. The state laws vary widely, making the categories in Tables 1-4 a sometimes uncomfortable fit with the structure of a given state's statute. Additionally, the comparison offered below has other important limitations. First, the issues aren't easily separable. For example, provisions that affect an individual's control over use of his genetic information (a privacy right) are often found within provisions prohibiting insurer or employer misuse of genetic information. The right to control your employer's disclosure of your genetic test results may not extend to your health care insurer. Secondly, this analysis focuses on legislation specifically enacted to protect against misuse of genetic data. The survey does not put the genetic-specific legislation into the broader context of protections against discrimination that exist in each state. These state insurance and employment discrimination provisions vary widely, and are outside the scope of this analysis. A final caveat worth noting is that this summary looks at state statutes without consideration of agency regulations, policy statements, or case law that might alter the legal environment surrounding privacy and discrimination issues in each state.

Health Insurance:

As of the summer of 2001, all but 7 or 8 states had enacted genetic-specific health insurance legislation that restricted the use of genetic information in determining eligibility for health care insurance. (Please see Table 1.) Some states provide less protection. For example, three states' legislation provides only that genetic information, cannot be considered a pre-existing condition by health insurers unless it is associated with a diagnosis. These states are Idaho, Nebraska, and North Dakota. Washington has no genetics-specific discrimination or privacy legislation, however WAC 284-43-720 (Guaranteed issue and restrictions on the denial, exclusion, or limitation of health benefits for pre-existing conditions) applies to all insurers in Washington and states "genetic information shall not be treated as a health condition in the absence of a diagnosis of the condition related to such information." While many states regulate the use of genetic information in group and individual policies offered by insurance companies, about one fourth of the state statutes apply to either individual or group insurance plans, leaving the other plans unregulated. Additionally, federal law preempts regulation of employer-sponsored benefit plans, so state laws only reach health insurance policies that are not employer-based. Of the 46 states with some regulation of health insurance use of genetic information, approximately 40 states prohibit the use of genetic information for selection or risk classification purposes. Smaller numbers of states restrict the collection of genetic test results, and 25 states require informed consent prior to disclosure of patient genetic information.

Life and Disability Insurance:

In general, the states appear more willing to accept use of genetic information by life, disability, or long-term care insurance companies than they are health care insurance companies. Seventeen states regulate the use of genetic information in these insurance decisions in some manner, as summarized in Table 2. While a handful of states flatly prohibit use of genetic information to deny or rate coverage, more states place limitations on the use of genetic information or genetic test results. Four states limit use of genetic information without justification by actuarial projections that establish that a difference in claims is likely. (Arizona, New Jersey, Montana and New Mexico take this approach.) In regards to use of genetic information, North Carolina regulates only life insurance, Wyoming law applies only to disability insurance, and other states such as Maine ban discrimination in life, disability, and long-term care insurance. As in the health insurance setting, some states have limited the scope of their legislation in other ways, such as Colorado, which bans genetic discrimination in group disability and long-term care insurance policies.

Employment nondiscrimination:

Like insurance laws, genetics laws that prohibit employment discrimination vary in coverage, protections, and penalties. Many states regulate the use of genetic information for determining hiring or terms of employment decisions. The states' genetic nondiscrimination laws pertaining to employment are summarized in Table 3. Delaware

and Illinois, for example, limit employer use of genetic data, without regulating their ability to obtain employee genetic information. Other state laws regulate both the use of genetic testing in employment decisions and access to genetic test results. These state laws generally prohibit employers from requiring workers and applicants to undergo genetic testing as a condition of employment. (Connecticut, New Hampshire and Nevada are examples of states including such a provision.) Massachusetts and Rhode Island employment nondiscrimination provisions are particularly expansive in scope.

Some states provide for exceptions to nondiscrimination provisions, allowing employers' use of genetic information in certain circumstances. Investigation of a worker's compensation claim, determination of a worker's susceptibility to potentially toxic chemicals in the workplace, or a bona fide occupational qualification are various examples of exceptions drafted into state genetic nondiscrimination legislation. Nevada's statute contains many of these exceptions. Other states have incorporated only one or two of these permitted uses of genetic information. These statutes often require the worker to provide informed written consent for such testing, contain specific restrictions governing disclosure, and prevent the employer from taking adverse action against the employee.

Privacy or Property Rights in Genetic Information:

Genetic privacy laws in approximately 27 states require informed consent from the individual in either the case of genetic testing or acquisition, disclosure, or retention of genetic information by a third party. (See Table 4.) These privacy protections are integrated into nondiscrimination legislation in some states. (Massachusetts, for example.) In other states, the privacy provisions stand alone. (See, for example, Florida or Illinois legislation.)

Privacy legislation gives an individual control over his genetic information. Often statutes require informed consent to perform or require a genetic test, or to obtain, retain, or disclose genetic information. Twenty-five states require consent for disclosure of genetic information. Of those 25 states, 13 go further to grant additional privacy rights in genetic information. Two states, Michigan and South Dakota, require informed consent to perform or require a genetic test, but do not regulate disclosure of genetic information once it is acquired.

Colorado, Georgia, Florida, and Louisiana are the only four states that create a personal property interest in genetic information. These laws state that genetic information is the "exclusive property" or "unique property" of the individual to whom the information pertains. Interestingly, one state that had previously recognized an individual's property interest in her genetic information later reversed itself. In 2001, Oregon repealed the property right that it had granted individuals in their genetic samples and genetic information.

Conclusion:

State laws regarding collection and use of genetic information have proliferated with the advancement of the scientific knowledge regarding human genetics and the human genome. In response to concerns regarding genetic discrimination, many state's legislatures have acted to protect against employer and insurer misuse of genetic information. The federal government has also acted in limited ways to regulate the acquisition and use of genetic information by third parties. In the last decade, genetics legislation has been rapidly changing. There is currently an academic and policy debate over the appropriateness of genetic-specific legislation based on a "genetics exceptionalism" perspective. Additionally, the technology and scientific understanding of genetic tests and the underlying genetic information they can convey is constantly evolving. It is therefore likely that genetics legislation will continue to adapt rapidly to adjust to these changing circumstances.

Selected Bibliography and Resource Guide:

National Conference of State Legislatures: www.ncsl.org/programs/health/genetics.htm

- *Contains a comprehensive, up-to-date comparison of states' genetics legislation. Additionally, the site tracks pending legislation (updated throughout the year) regarding genetic privacy and discrimination issues. Within the tables comparing state laws, are statutory sites with hyperlinks to the statutes of each state online.*

Sachin H. Jain, State Initiatives in Health Care Reform: Understanding the Genetic Code: State Genetic Information Laws, (Alpha Center 1999).

- *Contains comparisons of states' definitions of key legislative terms and also tables comparing legislation concerning: state protection of genetic information, health insurance, life/disability insurance, and employment discrimination. Appendix A of the report contains a helpful comparison of the various definitions of genetic test and genetic information used in the various state statutes. Additionally, Appendix B contains excerpts of statutory language, arranged alphabetically by state.*

Sonia M. Suter, The Allure and Peril of Genetics Exceptionalism: Do We Need Genetics Legislation? 79 Wash. U. L.Q. 669 (2001)

- The author examines the NCSL data, and takes a critical look at the policy and scientific rationales for genetics-specific legislation.

Council for Responsible Genetics: State Genetic Discrimination Legislation, available at http://www.gene-watch.org/programs/geneticdisc/gd_long_01pg2.html >

- *Contains the statutory cites and text for genetic legislation from the 50 states, arranged alphabetically.*

National Human Genome Research Institute: Ethical, Legal, and Social Implications of Human Genetics Research (ELSI), legislative and policy information, available at http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/>

- *Contains two collections of state genetic information statutes: one contains abstracts of employment discrimination genetic information statutes from the 50 states, the other abstracts health insurance genetic information laws.*
- *Policy Recommendations of the National Human Genome Research Institute, available at http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/legelsi.html*

Human Genome Project Information: Genetics Privacy and Legislation, available at <http://www.ornl.gov/hgmis/elsi/legislat.html>>

State Genetics Reports:

- IL: The Challenges of Human Cloning for Public Policy in Illinois (February 2001) available at <<http://www.igpa.uillinois.edu/publications/pdf/CloningReport.pdf>>
- OR: Assuring Genetic Privacy in Oregon (November 2000), available at <http://www.ohppr.state.or.us/genetic/GRAC_final.pdf>
- NY: Genetic Testing and Screening in the Age of Genomics Medicine (November 2000), available at <<http://www.health.state.ny.us/nysdoh/taskfcr/screening.htm>>
- KY: Genetic Testing in Health, Life, and Disability Insurance in Kentucky (January 2000), available at <<http://www.lrc.state.ky.us/lrcpubs/Rr289.pdf>>
- MI: Report of the Michigan Commission on Genetic Privacy and Progress (February 1999), available at <<http://www.mdch.state.mi.us/mcgpp/final/>>
- NE: Report of the Nebraska Commission on Human Genetic Technologies Commission (December 1998), available at <<http://www.hhs.state.ne.us/ced/genrep.htm>>